IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

CAROLINE POLT and MONICA POLT, individually and as co-executors of the estate of JOANNE POLT, deceased,	:	CIVIL ACTION NO. 16-02362
Plaintiffs,	:	
v.	:	
SANDOZ, INC.,	:	
Defendant.	:	

M E M O R A N D U M

EDUARDO C. ROBRENO, J. APRIL 25, 2019

I. INTRODUCTION

This is a wrongful death suit founded on product liability. The litigation began on May 16, 2016. See ECF No. 1. Plaintiffs allege that Defendant was negligent with regard to its drug amiodarone, and bring claims of failure to warn and negligence per se. See ECF No. 64.

After several extensions and adjustments to the deadlines in the case, as the close of discovery was approaching, the parties had a discovery dispute. See ECF Nos. 78, 87, 101, 109. Plaintiffs alleged that Defendant produced

thousands of pages of documents a mere twenty days before the close of discovery. See ECF No. 109. Plaintiffs claimed they needed time to review the allegedly late-produced documents and to supplement their expert reports, and sought an additional 120 days for the review. Id. As such, Plaintiffs sought a modification to the scheduling order.

Defendant countered that Plaintiffs had been in possession of the documents all along because they had been produced to Plaintiffs' counsel over two years ago in two other lawsuits. ECF No. 113. Defendant argued that Plaintiffs had failed to show the requisite good cause needed to modify a scheduling order pursuant to Federal Rules of Civil Procedure 16(b)(4) and 29(b), and certainly no good cause for a 120-day extension. Id.

On March 18, 2019, the Court heard oral argument on the dispute. See ECF Nos. 118, 127. Plaintiffs stated they did not have access to certain documents from the other cases because their counsel had split off from the firm that had conducted that litigation. ECF No. 127 at 3-4; see also ECF No. 69 (showing that in June 2018, Plaintiffs' counsel filed a notice of his firm's name change).

Plaintiffs next explained that the parties had an agreement regarding the productions from the other cases and that any of those documents used in this case would be

specifically identified by Bates numbers. See ECF No. 127 at 4. Plaintiffs stated that although some documents were referenced in discovery responses, Defendant did not identify them by Bates number. Id. at 19-20, 28-29.

Defendant countered that its discovery responses had included specific Bates numbers, and provided an example in hard copy to the Court. Id. at 31 (The Court was handed a copy of Defendant's objections and responses to Plaintiffs' Second Set of Requests for Production of Documents, dated November 20, 2018). Defendant also argued that "plaintiff's theory of this case ha[d] been a moving target throughout," which had disrupted the orderly resolution of the litigation. Id. at 26-27.

During the hearing, the Court told Plaintiffs that they would be given time to review the documents and file a motion for leave to supplement the expert report. Id. at 33. Further, the Court required such a motion, if filed, to "include the proposed supplementation and an explanation -- a justification why a particular document or documents opened up a new vista to [the expert's] views." Id. After the hearing, the Court issued an Order to the same effect. ECF No. 117. The Court's Order stated that Plaintiffs' "brief in support of the motion must explain why such supplementation is necessary." Id. ¶ 3.

Plaintiffs timely filed their motion for leave to submit a supplemental expert report. ECF No. 119. Plaintiffs' briefing on the motion also states that Defendant produced an additional 45 documents after the March 18 hearing, and that Plaintiff seeks leave to file an additional report on these documents from a new expert. Id. Defendant timely opposed the motion. ECF No. 125. The motion is ripe for disposition.

II. LEGAL STANDARDS

Federal Rule of Civil Procedure 16(b) sets a "good cause" standard for modifying a scheduling order. Eichorn v. AT&T Corp., 484 F.3d 644, 650 (3d Cir. 2007); see also Chancellor v. Pottsgrove Sch. Dist., 501 F. Supp. 2d 695, 701-02 (E.D. Pa. 2007). The party seeking a modification must demonstrate that it was diligent. Chancellor, 501 F. Supp. 2d at 701-02; see also Fed. R. Civ. P. 16, advisory comm. note (1983) ("[T]he court may modify the schedule on a showing of good cause if it cannot reasonably be met despite the diligence of the party seeking the extension."); Inge v. Rock Fin. Corp., 281 F.3d 613, 625 (6th Cir. 2002) (holding that Rule 16(b)'s "good cause" standard focuses on a party's diligence); Johnson v. Mammoth Recreations, Inc., 975 F.2d 604, 609 (9th Cir. 1992) ("Rule 16(b)'s 'good cause' standard primarily considers the diligence of the party seeking the amendment."); 6A Charles A.

Wright & Arthur R. Miller, Federal Practice & Procedure § 1522.2 (3d ed.).

"Attorney neglect or inadvertence will not constitute good cause supporting modification." 6A Wright & Miller, Federal Practice & Procedure § 1522.2.

III. DISCUSSION

A. Dr. Sharlin's April Report

The issues in the case include whether in accordance with the federal regulations, adequate numbers of appropriate "Medication Guides" (package inserts and the like containing product information that typically accompany pharmaceutical products) were provided or made available to pharmacists who dispensed the drug amiodarone. See, e.g., FDA, Medication Guides (Aug. 8, 2018), https://www.fda.gov/Drugs/DrugSafety/ucm085729.htm (last visited April 25, 2019). Plaintiffs' expert, Dr. Joshua Sharlin, has offered his opinions on this and other issues.

Originally, Dr. Sharlin submitted a "supplemental" expert report dated February 12, 2019. See ECF No. 102-1 (bearing Bates numbers POLT-PEJS-000007 to -25). Plaintiffs have moved the Court to allow Dr. Sharlin to submit a new supplemental expert report comprising two parts. See ECF No. 119-3. The first part, dated April 5, 2019, is an edited version of Dr. Sharlin's report from February. See id. (bearing

Bates numbers POLT-PEJS-000026 to -46). The edited version contains an additional observation (#4) and has edits to other observations. The second part, dated April 8, 2019, is an addendum containing two new observations. See id. (bearing Bates numbers POLT-PEJS-000047 to -54).

Dr. Sharlin did not explain any of the changes to his main report or even indicate that he had made changes. For the addendum, Dr. Sharlin averred that the "addendum is written in response to additional regulatory information made known by Sandoz on 22Feb2019." ECF No. 119-3 at POLT-PEJS-000049. Thus, at a minimum under the Court's Order, it fell to Plaintiffs' counsel to provide justifications for the edits to Dr. Sharlin's main report. However, Plaintiffs' counsel did not comply with the Court's Order requiring them to explain why the production and identification of documents "opened up a new vista" in Dr. Sharlin's views that would necessitate the changes to his main report. Instead, the briefing is markedly lacking in this regard and is poorly organized: far from providing clarity, it is opaque; far from providing substance, it is hollow; and far from being candid, it seeks to mislead.

The Court address in turn the principal arguments made by Plaintiffs.

1. The new documents show that Defendants "did not provide 'bulk' Medication Guides," making the "nature of how the warning or Medication Guides were provided . . . now a crucial element"

In support of this proposition, Plaintiffs cite two documents, docketed as Exhibit B to the motion and bearing Bates numbers SANDOZ-AMIO-QAPS-020877 and SANDOZ-AMIO-QAPS-020878. But Plaintiffs do not explain what changes were made in the report on the basis that it received these two documents.

Plaintiffs state that the "nature and type of warnings contained in the Medication Guide and manner of providing them are now new issues before the Court." ECF No. 119 at 2 (emphasis added).

That statement is not correct. Plaintiffs' Third Amended Complaint shows that the nature and type of warnings in the Medication Guides were always at issue, as was the manner in which Defendant provided the Guides. See ECF No. 64. Indeed, in the averred causes of action, Plaintiffs allege:

> The death of Joanne Polt was directly and proximately caused by the Defendant's negligent failure to provide appropriate warnings in the form of the up to date and required labeling and the negligent failure to ensure distribution of the Medication Guides . . . .
>
> The death of Joanne Polt was directly and proximately caused by the Defendant's negligent failure to warn and provide mandated warnings in the form of up to date and required labeling and the failure to provide the Medication Guides . . . .

Id. ¶¶ 71, 79.

Further undercutting Plaintiffs' assertion in the brief, Dr. Sharlin's February 2019 report makes observations about the content of the Medication Guides and how they were supplied, and provides his opinions as to the same. See, e.g., ECF No. 102-1 at POLT-PEJS-000009 ("Sandoz's errors in executing Medication Guide regulations means they failed to follow FDA requirements intended to deliver Medication Guides to distributors, packers, or authorized dispensers in sufficient numbers or provide the means to do so (Reprint #5)."); POLT-PEJS-000013 ("Sandoz's processes supporting the distribution and dispensing of Medication Guides violate 21 CFR 211.122(a) (Reprint #4) . . . ."); POLT-PEJS-000015 ("Sandoz's processes supporting the distribution of an electronic version of a Medication Guide violate 21 CFR 11 regulations (Reprint #7) . . . ."); POLT-PEJS-000024 ("Sandoz's errors in executing Medication Guide regulations means they failed to follow FDA requirements intended to deliver Medication Guides to distributors, packers, or authorized dispensers in sufficient numbers or provide the means to do so (Reprint #5)."); POLT-PEJS-000024 ("Sandoz's process for supplying an Amiodarone Medication Guide to the Plaintiff fail to comply with the FDA regulations addressing drug label compliance . . . ."); POLT-PEJS-000025 ("Sandoz's errors in executing Medication Guide

regulations means there is a failure to follow FDA requirements intended to deliver Medication Guides to distributors, packers, or authorized dispensers in sufficient numbers or provide the means to do so . . . .").

Plaintiffs' first argument in support of the edits fails because it is simply not true.

2. The new documents reveal "additional evidence of FDA regulatory compliance failures"

By way of much-needed clarity, the Court discusses whether the "new documents" justify the edits to the main report before turning to whether they justify an addendum.

a) Main Report

Whether or not the review of the documents revealed "additional evidence of FDA regulatory compliance failures," Plaintiffs failed to explain which edits to the main document were necessitated.

Plaintiffs reference an "internal Sandoz Medical Inquiry Detail report from July 2008," and pithily mention observation #6 of the February report. ECF No. 119 at 3. But in the April report, the corresponding observation (#7) appears to be unchanged, save for the title, and in any case the observation cites no documents. Plaintiffs have failed to justify any edits to the main report based on this argument.

Plaintiffs state that "there is no documentation that the complaint handling process" was applied to the documents. Id. Plaintiffs argue that the lack of documentation "reinforces the conclusions about no complaint handling documentation noted in observation #3" of the February report. Id. But that discussion in the April report is unedited. Plaintiffs have failed to justify any edits to the main report based on this argument.

Plaintiffs state that "a review of nearly 500 Packaging Work Orders . . . revealed no information about a methodology for calculating the number of Medication Guides to be shipped with the drug." Id. at 4. According to Plaintiffs, "[t]his is additional confirmation of a conclusion in observation #4 in Dr. Sharlin's February 12, 2019 expert report . . . ." Id. In the April report's corresponding observation (#5), two paragraphs have been deleted without explanation. Compare ECF No. 102-1 with ECF No. 119-3. To the extent that the review of the documents resulted in "additional confirmation," there is no need for the edits to this observation. Indeed, the observation makes no reference to any document. Plaintiffs have failed to justify any edits to the main report based on this argument.

The major edit to the main report appears to be the addition of what is now observation #4. This observation is

titled "Sandoz is Inconsistent and Without a Written Procedure for Calculating the 'Sufficient Numbers' of Medication Guides that Must be Included in a Shipment of Amiodarone." ECF No. 119-3 at POLT-PEJS-000032. The observation refers to only one document, a "Changes Being Effected" document (CBE letter) which was sent by Defendant to the FDA, and bearing Bates number SANDOZ-AMIO-FDACORR-006260. See id. at POLT-PEJS-000033.

A critical part of Plaintiffs' argument for allowing supplementation was that Defendant had not identified by Bates number the documents that were responsive to Plaintiffs' discovery requests. But that is not the case with the document cited in observation #4 of the April report. Perhaps serendipitously for Defendant, the discovery responses handed to the Court during the hearing show that since at least November 20, 2018, this document had been specifically identified to Plaintiffs. See Defendant Sandoz Inc.'s Objections and Responses to Plaintiffs' Second Set of Requests for Production of Documents at Responses to Requests Nos. 2, 3, 5, and 6 (Nov. 20, 2018). Plaintiffs' argument is baseless in regard to observation #4 in the April report.

b) Addendum

Plaintiffs failed to clearly explain any aspect of the proposed addendum. The first observation in the addendum cites and discusses two documents bearing Bates numbers SANDOZ-AMIO-

QAPS-020786 and SANDOZ-AMIO-QAPS-020803. The first of these appears to be the July 2008 "Medical Inquiry Detail" report. See ECF No. 119-3 at POLT-PEJS-000051. The second observation in the addendum cites no documents, however, it appears to be logically connected to the first observation. Plaintiffs did not explain why these documents, or any other document, necessitated the new observations. The substance of the observations do not appear to be covered by the observations made in the main report.

Defendant challenges the addendum as being "a misapprehension and/or deliberate distortion of [the cited] documents." ECF No. 125 at 6-7. Defendant argues that the obsevations and opinions in the addendum are inconsistent with deposition testimony referenced by Dr. Sharlin in his February report. Id. at 12-15.

Defendant's argument goes to the merits of Dr. Sharlin's addendum. But the question here is whether Dr. Sharlin could have provided the substance of the addendum without the documents that were "newly" provided. Unlike the CBE letter discussed above, Defendant did not show that Plaintiffs had already received specific notice of these documents.

The Court must conclude that Defendant failed to follow the agreement about referencing documents from

productions in other cases, and so Dr. Sharlin should be given an opportunity to provide his opinions on this aspect. Defendant may respond to the merits of Dr. Sharlin's addendum in a rebuttal report, and will be afforded the opportunity to depose Dr. Sharlin on the addendum.

3. Conclusion as to Dr. Sharlin's April Report

Odysseus himself would recognize Dr. Sharlin's edited main report for what it is -- the written equivalent of a Trojan horse by which Plaintiffs would sneak in new expert opinions. And despite clear instructions to explain how the "newly identified" documents necessitated any changes, Plaintiffs failed to do so in regard to the main report. The Court will not allow Plaintiffs to submit an edited main report.

On the other hand, Defendant failed to show that it had previously identified the specific documents upon which the addendum is based. Defendant did not follow the parties' agreement to identify by Bates number the responsive documents from the other litigations. While Plaintiffs' counsel admitted to failing to follow up on the issue, Defendant nevertheless had the obligation to provide the information in the first place. The addendum will be allowed to augment the February 15, 2019 report.

Accordingly, Dr. Sharlin's February 2019 report (bearing Bates numbers POLT-PEJS-000007 to -25) and the addendum

(bearing Bates numbers POLT-PEJS-000047 to -54) shall stand as Dr. Sharlin's Rule 26 disclosures. Defendant may submit a rebuttal report that is limited to the substance of the addendum, and may depose Dr. Sharlin on the addendum. Plaintiffs may depose an expert who offers a rebuttal report on the addendum.

B. Entirely New Report

Plaintiffs did not submit an expert report that addresses the 45 late-produced documents.

Plaintiffs state that a new, unnamed expert should be allowed to submit a report on the 45 documents (> 3,000 pages) that were produced after March 18, 2019. Plaintiffs argue that these documents "catalog [Defendant's] failures to provide the latest versions of [the drug medication guides] to patients and pharmacists." ECF No. 119 at 4.

Plaintiffs may be correct, but little other information is provided. Furthermore, there is no explanation as to who their expert is, the expert's qualifications, or why one of their existing flock of experts cannot provide a supplemental report on this issue.

Defendant responds that the Court's Order of March 18, 2019 did not allow Plaintiffs the opportunity to submit an entirely new expert report. But Defendant ignores the fact that the documents were produced after the hearing, so the Court

could not have ordered anything in regard to these documents. Defendant's letter that accompanied the late production explained how these documents were responsive to Plaintiffs' Requests for Production Nos. 1, 2, and 4.

Plaintiffs have not made much of an argument here, but Defendant produced these documents very late. To the extent that the opinions contained in a "new expert's" report are based on the 45 documents produced after the March 18, 2019 hearing, and to extent the substance of these documents provide a genuinely new area of discussion, the new opinions will be allowed. But if the content of the 45 documents merely goes to supporting observations and opinions already provided, no new report will be allowed. Of course, in the event a new report is submitted, Defendant will be entitled to depose the expert, whoever he or she may be, as to any opinion offered on the 45 late-produced documents.

IV. CONCLUSION

The discovery dispute centered on Defendant's allegedly late production of documents. The Court is unable to determine the extent of this late production. Nevertheless, it appears that at least some documents were "late," either because they had never been produced or they had not been specifically identified pursuant to the parties' agreement. Accordingly, Plaintiffs shall be given an opportunity to submit expert

reports as to those documents. Put another way, the Court finds that Defendant's failure to produce documents on time is good cause for Plaintiffs to supplement the expert reports in regard to the late-produced documents, but there is no basis to allow any other edits.

The Court acknowledges that the late production of documents sometimes happens in complex and voluminous litigation. However, no fewer than nine attorneys have entered an appearance on behalf of Defendant. Under these circumstances, there is no excuse for the late production or identification of documents. The Court expects that all responsive documents have now been produced or identified pursuant to the parties' agreement.

It also appears, sadly, that Plaintiffs have tried to use this opportunity to sneak in unwarranted edits by misrepresenting to the Court that there was a valid basis for such edits. This conduct is unacceptable. Let this serve as a clear warning -- no further such behavior will be tolerated.